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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,616	10/04/2001	Jerome Soupe	U-013614-4	2713

140 7590 10/02/2002

LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
1761	12

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/970,616	SOUFFE ET AL.
	Examiner Keith Hendricks	Art Unit 1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 9-17 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 9-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/230,590.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,8</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on October 04, 2001, have been accepted.

Claim Rejections - 35 USC § 112

- i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the transformation and regeneration of barley plant seeds expressing the product of one or more of the enzyme genes of endo- β -(1,4)-xylanase, arabinofuranosidase, alpha-amylase, endo-protease, or a β -(1,3-1,4)-glucanase, does not reasonably provide enablement for the transformation and regeneration of any random plant seed other than barley, expressing said enzyme genes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A number of factors must be considered in assessing the enablement of an invention, including the following: the breadth of the claims, the amount of experimentation necessary, the guidance provided in the specification, working examples provided, predictability, and the state of the art. See *In re Wands*, 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Circ. 1988).

The production of recombinant host cells, both prokaryotic and eukaryotic, plant and mammalian included, was well within the recognized level of skill in the art at the time the invention was made. The production of any random plant host, and the production of seeds therefrom, however, was not. The production of transgenic plants, as encompassed by the claims, even at present, was and is a highly unpredictable and problematic technology. Several complications arise concerning the effective incorporation of the DNA into the system, as well as its proper expression and function within the host system itself. The rejected claims are not even directed to any specific host, other than any of the thousands of known plants seeds.

While claims 15-17 are limited to a barley plant seed expressing the enzymes, no source of each of the enzyme genes is provided, either in the claims or the specification. Genes from eukaryotes are

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expressed differently in hosts than those from prokaryotes, and a crossing of these lines provides further complications of proper translation and expression in the host's cells. Further, even if some success was attained in transforming certain other plant lines, there is no predictable expectation of success that the seeds of said plant(s) would effectively and functionally express the required enzyme activity. Not all genes of a plant are expressed in its seeds, and different plants are able to express certain genes more effectively than others. Finally, it is noted that only very few plant seeds are actually useful in brewing processes, mainly barley, hops and wheat, and therefore the transformation and expression of said enzymes in other plant seeds would not necessarily prove successful in the claimed process. Other than the discussion of barley transformation and the use of barley seeds expressing the enzyme(s) at Examples 9 and 12, no working examples have been provided, and therefore it would have been highly unpredictable, with an extreme amount of undue experimentation, for one skilled in the art to blindly attempt to produce the invention as broadly claimed.

ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "wherein the component or components comprise a seed", for example in claim 9, does not clearly set forth the metes and bounds of the claimed invention. The functional and spatial relationship of the seed to the "component or components", is unclear. It is unclear if the component is a mixture of enzymes with a random seed included therein, or if the seed contains the enzymes, etc.

The phrases "that sets seed containing" (claims 10 & 14) and "setting seed containing" (claim 12), are confusing in the context of the claim. This is due, in part, to the term "sets".

In claims 11-12, the phrases "the components" and "said components", lack a clear antecedent basis within the claims. These claims depend from claim 9, which provides for a "component or components", not "said components." No intervening claim limits the invention to "the components."

NOTE: In claim 9, line 4, the term "xylanases" should be "xylanase".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



KEITH HENDRICKS
PRIMARY EXAMINER